DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2015

Jawon Medical Co., Ltd.
% Woo Park
Director
Medmonts Co., Ltd.
Life-Officetel 320, 40, 63-ro
Youngdeungpo-Gu
Seoul, 150-731 KR

Re: K140762
Trade/Device Name: Automatic Blood Pressure Monitor, Model EX PLUS 1300
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 20, 2014
Received: May 20, 2015

Dear Woo Park,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

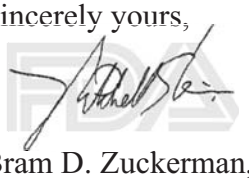
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Doc.No.: 012

#1208-12, Sinsang-ri, Jinryang-eup, Kyungsan-city,
Kyungsang-Bukdo, 712-830, Republic of Kora
Tel:82-53-856-0993, Fax:82-53-856-0995

JAWON MEDICAL
www.jawon.com

Indications for Use

510(k) Number: 140762

Device Name: Jawon Automatic Blood Pressure Monitor
Model EX PLUS 1300

Indications for use

The Jawon Upper Arm Automatic Digital Blood Pressure Monitor, Model EX PLUS 1300 is for use by medical professional or home user. The EX PLUS 1300 is a device intended to measure the systolic and diastolic blood pressure, pulse rate and mean blood pressure and inter-arm pressure difference of an adult individual by using a non-invasive oscillometric technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s). The cuff size is fit for arm circumference of 23-36 cm.

Contraindications for use

As with any non-invasive measurement device, there are clinical conditions which can influence the accuracy of the results. Also, the subject's position, physiological condition and other environmental factors can affect the measurement/calculation.
The EX PLUS 1300 Non-Invasive Blood Pressure Monitor should not be used with patients who have the following conditions:

1. Patients with a known arrhythmia.
2. Patients with insufficient peripheral circulation, acute cases of low blood pressure or low temperature.
3. Patients who use a pacemaker.
4. Patients experiencing a seizure.
5. Children younger than 18 years old.
6. Patients who should not have blood pressure measurements taken from their arms.
7. Patients with an artificial heart.
8. Patients whose artery cannot be found by palpation.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

#1208-12, Sinsang-ri, Jinryang-eup, Kyungsan-city,
Kyungsang-Bukdo, 712-830, Republic of Korea
Tel: 82-53-856-0993, Fax: 82-53-856-0995

510(k) Summary

[As Required by 21 CFR 807.92]

K140762

Date Prepared: Mar.20, 2014

Submitter: Jawon Medical Co., Ltd.
#1208-12, Sinsang-ri, Jinryang-eup, Kyungsan-city, Kyungsang-Bukdo, 712-830, Republic of Korea
Tel:82-53-856-0993, Fax:82-53-856-0995
Establishment Registration Number: 9616164

Contact Person: MEDMONTS Co., Ltd. (Mr. W.S.Park)
Life-officetel 320, 40 63-ro, Youngdeungpo-gu, Seoul, 150-731, Republic of Korea
Tel:82-2-6264-9001, Fax: 82-2-6269-9001
E-mail: wpark19@gmail.com

Trade Name: Automatic Blood Pressure Monitor
Model EX PLUS 1300

Common Name: Non-invasive Blood Pressure Monitor

Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN

Predicate Device: Automatic Blood Pressure Monitor
Jawon Model EASY X 900(R/L)_(K092432)

Device descriptions:
The EX PLUS 1300 is a blood pressure monitor to non-invasively measure blood pressures and heart rate at the brachial site(s). The device employs oscillometric method. The device is a microprocessor-controlled and includes an air pump, an electronic valve to regulate deflation rate, circuitry to detect and process minute pressure oscillations, LCD display of systolic and diastolic pressure readings and heart rate, and push buttons.
The device employs a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. The electronic deflation control valve maintains the deflation rate within limits of 3 to 5 mmHg/sec to optimize measurement accuracy.
The EX PLUS 1300 is an AC adapter-powered.

Indications for use
The Jawon Upper Arm Automatic Digital Blood Pressure Monitor, Model EX PLUS 1300 is for use by medical professional or home user. The EX PLUS 1300 is a device intended to measure systolic and diastolic blood pressures, pulse rate and mean blood pressure, and inter-arm pressure difference of an adult individual using a non-invasive oscillometric technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s). The cuff size is fit for arm circumference of 23-36 cm.

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Kyungsang-Bukdo, 712-830, Republic of Korea
Tel: 82-53-856-0993, Fax: 82-53-856-0995
www.jawon.com

Contraindications for use

As with any non-invasive measurement device, there are clinical conditions which can influence the accuracy of the results. Also, the subject's position, physiological condition and other environmental factors can affect the measurement/calculation.
The EX PLUS 1300 Non-Invasive Blood Pressure Monitor should not be used with patients who have the following conditions:

1. Patients with a known arrhythmia.
2. Patients with insufficient peripheral circulation, acute cases of low blood pressure or low temperature.
3. Patients who use a pacemaker.
4. Patients experiencing a seizure.
5. Children younger than 18 years old.
6. Patients who should not have blood pressure measurements taken from their arms.
7. Patients with an artificial heart.
8. Patients whose artery cannot be found by palpation.

Technologic characteristics:

The modified device EX PLUS 1300 has the same intended use and technology characteristics as predicate device EASY X 900 (R/L). The differences in this submission don't raise new questions concerning either safety or effectiveness.

Comparison with Predicate Device:

The EX PLUS 1300 was compared with the EASY X 900(R/L) of which is the predicate device. The intended use of both models are same except that the subject device EX PLUS 1300 can measure both arms at the same time. Patient and/or physician can compare the blood pressures between right and left arms. The principle of operation and operating features are identical. Both the subject device and the predicate device incorporate a thermal printer. In terms of the product construction, the model EX PLUS 1300 is comprised of two (2) sets of model EASY X 900(R/L) in one enclosure.

Subject device (model-Jawon EX PLUS 1300)	Predicate Device (model-Jawon EASY X 900(R/L)
One or two inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s).	One inflatable cuff is wrapped around the single upper arm

Non-clinical and Clinical Tests:

The modified device EX PLUS 1300 meets the requirements of IEC 60601-1 and IEC 60601-1-2. The EX PLUS 1300 was not clinically tested because the device uses the identical software codes and pressure detection related hardware as the predicate device to determine systolic, diastolic, and pulse rate.

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Performance Specifications:

Characteristic	Model EX PLUS 1300
Mesurement method	Oscillometric
Measurement range – pressure	30 to 280 mmHg
Measurement range – heart rate	30 to 200 bpm
Accuracy – pressure	+/- 2mmHg
Accuracy – heart rate	+/- 3%
Temperature limits	+10℃ t0 40℃
Humidity limits	Less than 95%
Power	110-120 VAC, 60Hz
Display mode	Digital LCD screen

Software Testing Software for the Model EX PLUS 1300 was designed and developed according to a robust software development process, and was rigorously verified and validated.

Clinical Performance: As the modified device EX PLUS 1300 comprises of two sets of EASY X 900(R/L) of which are predicate device, no clinical test was conducted.

Conformance Assessment: Risk analysis and necessary V&V activities was performed to demonstrate that the design outputs of the modified device meet the design input requirements.

Conclusions:

We have demonstrated that there are no significant differences between the Jawon Upper both arm automatic digital blood pressure monitor, Model EX PLUS 1300 and the predicate device, Model EASY X 900(R/L), in terms of safety and effectiveness based on electrical, and EMC test results per IEC 60601-1 and IEC 60601-1-2, and the ANSI/AAMI Voluntary Standard, SP-10:2008.